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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,059	09/23/2003	Victor Schoenle	10527-477001	2738
26161	7590	04/06/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			AUGHENBAUGH, WALTER	
			ART UNIT	PAPER NUMBER
			1772	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,059

Applicant(s)

SCHOENLE ET AL.

Examiner

Walter B. Aughenbaugh

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74,76-84,86-92,94-104,106-118 and 120-139 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74,76-84,86-92,94-104,106-118 and 120-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/09/06, 01/11/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Acknowledgement of Applicant's Amendments

1. The amendments made in claims 74, 78-80, 82-84, 88, 89, 91, 92, 96-99, 101-104, 108-112, 114-118, 122-125 and 127-129 in the Amendment filed on January 3, 2006 (Amdt. A) have been received and considered by Examiner.
2. New claims 130-139 have been received and considered by Examiner.

WITHDRAWN REJECTIONS

3. The 35 U.S.C. 102 rejection of claims 74-78, 80-82, 104-109, 112-115, 118-123 and 125-128 has been withdrawn due to Applicant's amendments in claims 74, 80, 104, 112, 118 and 125 in Amdt. A.
4. The 35 U.S.C. 103 rejection of claims 79, 83, 110, 116, 124 and 129 has been withdrawn due to Applicant's amendments in claims 74, 80, 104, 112, 118 and 125 in Amdt. A.
5. The 35 U.S.C. 103 rejection of claims 87 and 90 has been withdrawn due to Applicant's amendments in claims 84 and 89 in Amdt. A.

REPEATED REJECTIONS

Claim Rejections - 35 USC § 112

6. The 35 U.S.C. 112, first paragraph rejection of claims 74-129 has been repeated for the reasons previously made of record and for the following reason that addresses the amendments in Amdt. A: in regard to claims 74-129, the specification does not indicate which polyesters listed in the paragraph bridging pages 12 and 13 of the specification satisfy which of the various mechanical property requirements listed on pages 2-5 of the specification.

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In further regard to claims 92-103, 111, 117, Applicant does not explain in the specification how the claimed "load at break ratio" is determined. The "load at break ratio" is mentioned only on pages 2 and 5 of the specification. While the method of determining all other claimed properties are disclosed on pages 10-12, 14, 15 and 24-26, the method of determining the claimed "load at break ratio" is not disclosed.

Claim Rejections - 35 USC § 102

7. The 35 U.S.C. 102 rejection of claims 84, 86, 88, 89 and 91 has been repeated for the reasons previously made of record and for the following reason that addresses the amendments in Amdt. A: Sahatjian et al. teach that the polymer is a polyester (PET, col. 1, lines 43-55).

NEW REJECTIONS

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 130-139 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not indicate what copolymers of polyesters (line 2 of page 13 of specification) satisfy which of the various mechanical property requirements listed on pages 2-5 of the specification.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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11. Claims 74, 80, 84, 89, 92, 99, 104, 112, 118 and 125 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "adapted to be bonded to a hypotube" renders the claim indefinite since the structure via which the region is "adapted to be bonded to a hypotube" cannot be ascertained.

Claim Rejections - 35 USC § 102

12. Claims 74, 76-78, 80-82, 106, 107, 113, 118, 120-123 and 125-128 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson et al.

In regard to claim 74, Robinson et al. teach a component of a medical device (combination of trunk, item 14, and leg extensions, items 16 and 18, col. 6, lines 30-33) that includes a region (graft 22, col. 6, lines 33-38, col. 7, lines 11-15 and Fig. 3) that comprises a polyester since Robinson et al. teach that the graft 22 is of a conventional vascular graft construction (col. 7, lines 13-15), and polyesters are used for vascular grafts as evidenced by U.S. 4,695,280 to Watanabe et al. at col. 3, lines 1-3. Polyester resin has a tensile strength of 21,000 psi as evidenced by US 3,969,176 to Bassett et al. at col. 5, lines 32-37. Graft 22 of Robinson et al. is tube-shaped (Fig. 3).

In regard to claim 80, Robinson et al. teach a tube-shaped portion of a catheter including a region comprising a polyester since Robinson et al. teach that the graft 22 is of a conventional vascular graft construction (col. 7, lines 13-15), and polyesters are used for vascular grafts as evidenced by U.S. 4,695,280 to Watanabe et al. at col. 3, lines 1-3. Polyester resin has a tensile strength of 21,000 psi as evidenced by US 3,969,176 to Bassett et al. at col. 5, lines 32-37. Graft 22 of Robinson et al. is tube-shaped (Fig. 3).

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In regard to claims 118 and 122, Robinson et al. teach a component of a medical device (combination of trunk, item 14, and leg extensions, items 16 and 18, col. 6, lines 30-33) that includes a region (graft 22, col. 6, lines 33-38, col. 7, lines 11-15 and Fig. 3) that comprises a polyester since Robinson et al. teach that the graft 22 is of a conventional vascular graft construction (col. 7, lines 13-15), and polyesters are used for vascular grafts as evidenced by U.S. 4,695,280 to Watanabe et al. at col. 3, lines 1-3. Polyester resin has a post buckle fracture tensile strength of at least about 15,000 psi as evidenced by US 3,969,176 to Bassett et al. at col. 6, lines 12-16. Graft 22 of Robinson et al. is tube-shaped (Fig. 3).

In regard to claims 125 and 127, Robinson et al. teach a tube-shaped portion of a catheter including a region comprising a polyester since Robinson et al. teach that the graft 22 is of a conventional vascular graft construction (col. 7, lines 13-15), and polyesters are used for vascular grafts as evidenced by U.S. 4,695,280 to Watanabe et al. at col. 3, lines 1-3. Polyester resin has a post buckle fracture tensile strength of at least about 15,000 psi as evidenced by US 3,969,176 to Bassett et al. at col. 6, lines 12-16. Graft 22 of Robinson et al. is tube-shaped (Fig. 3).

In regard to claims 76, 106 and 120, Robinson et al. teach that the component is a catheter (Fig. 1-3).

In regard to claims 77, 81, 107, 113, 121 and 126, Robinson et al. teach that the component (combination of trunk, item 14, and leg extensions, items 16 and 18, col. 6, lines 30-33, Fig. 3) has a first layer (trunk, item 14) and a second layer (leg extensions, items 16 and 18) where the first layer has a different flexibility from the second layer (since the two layers have different diameters, the two layers necessarily have different flexibilities).

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In regard to claims 78 and 82, polyester resin has a tensile strength of 30,000 psi as evidenced by US 3,969,176 to Bassett et al. at col. 5, lines 27-30 and col. 1, lines 32-37.

In regard to claims 123 and 128, Polyester resin has a tensile strength of 21,000 psi as evidenced by US 3,969,176 to Bassett et al. at col. 5, lines 32-37.

Claim Rejections - 35 USC § 103

13. Claims 79, 83, 124 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. in view of Sahatjian et al.

Robinson et al. teach the component and tube-shaped portion as discussed above.

Robinson et al. fail to teach that the polyester has a hoop stress of at least about 3300 psi.

Sahatjian et al. teach a balloon (col. 2, lines 32-35) comprising polyester (col. 1, lines 43-51) where the polyester has a hoop stress greater than about 36,000 psi (col. 1, lines 50-51, col. 7, lines 38-48 and col. 8, lines 16-18). Therefore, one of ordinary skill in the art would have recognized to have used the polyester that has a hoop stress greater than about 36,000 psi of the balloon of Sahatjian et al. as the polyester of Robinson et al. since a material that has a hoop stress greater than about 36,000 psi is a well known suitable material for use as the material of a component of a medical device as taught by Sahatjian et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the polyester that has a hoop stress greater than about 36,000 psi of the balloon of Sahatjian et al. as the polyester of Robinson et al. since a material that has a hoop stress greater than about 36,000 psi is a well known suitable material for use as the material of a component of a medical device as taught by Sahatjian et al.

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14. Claims 87 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian et al. in view of Pinchuk et al.

Sahatjian et al. teach the balloon as discussed above in the 35 U.S.C. 102 rejection of claims 84, 86, 88, 89 and 91 above.

Sahatjian et al. fail to teach that the balloon comprises a first layer and a second layer where the first layer has a different flexibility from that of the second layer.

Pinchuk et al., however, teach that balloons can be coated with non-thrombogenic Pinchuk et al., however, teach that balloons can be coated with non-thrombogenic lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that balloons can comprise a first layer and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layers necessarily have different flexibilities). Therefore, one of ordinary skill in the art would have recognized to have coated the balloon of Sahatjian et al. with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the balloon of Sahatjian et al. with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

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Response to Arguments

15. Applicant's arguments regarding the 35 U.S.C. 112 rejection of claims 74-129 have been fully considered but are not persuasive. The specification does not indicate which polyesters listed in the paragraph bridging pages 12 and 13 of the specification satisfy which of the various mechanical property requirements listed on pages 2-5 of the specification. In further regard to claims 92-103, 111, 117, Applicant does not explain in the specification how the claimed "load at break ratio" is determined. The "load at break ratio" is mentioned only on pages 2 and 5 of the specification. While the method of determining all other claimed properties are disclosed on pages 10-12, 14, 15 and 24-26, the method of determining the claimed "load at break ratio" is not disclosed.

16. Applicant's arguments in Amdt. A regarding the 35 U.S.C. 102 rejection of claims 74-78, 80-82, 104-109, 112-115, 118-123 and 125-128 are moot due to the withdrawal of the rejection in this Office Action.

17. Applicant's arguments in Amdt. A regarding the 35 U.S.C. 103 rejection of claims 79, 83, 110, 116, 124 and 129 are moot due to the withdrawal of the rejection in this Office Action.

18. Applicant's arguments regarding the 35 U.S.C. 102 rejection of claims 84-86, 88, 89 and 91 in Amdt. A have been fully considered but are not persuasive. Applicant's argument that it is "unclear" whether the hoop stress at failure of Sahatjian is the same as the hoop stress of Applicant is inconclusive. Applicant's argument that "Sahatjian is referring to a region of his device that is not adapted to be bonded to a hypotube" is not supported: Applicant does not explain why the balloon is not "adapted to be bonded to a hypotube" or what structure "adapted to be bonded to a hypotube" is intended to recite.

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19. Applicant's arguments regarding the 35 U.S.C. 103 rejection of claims 87 and 90 in Amdt. A have been fully considered but are not persuasive. Applicant's argument that it is "unclear" whether the hoop stress at failure of Sahatjian is the same as the hoop stress of Applicant is inconclusive. Applicant's argument that "Sahatjian is referring to a region of his device that is not adapted to be bonded to a hypotube" is not supported: Applicant does not explain why the balloon is not "adapted to be bonded to a hypotube" or what structure "adapted to be bonded to a hypotube" is intended to recite.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-

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1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is to 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
04/03/06

WBA


HAROLD PYON
SUPERVISORY PATENT EXAMINER
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4/3/06